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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,453	03/06/2002	Roberto Cecchi	IVD 1135	5554

27546 7590 12/03/2003
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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,453

Applicant(s)

CECCHI ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-12 and 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 6 and 7 is/are allowed.
- 6) ☐ Claim(s) 1-5, 8, 10-12, 14-26 is/are rejected.
- 7) ☐ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Response and amendment filed by applicants in paper No. 6, dated Oct. 27, 2003 have been entered and considered carefully. Claims 13 has been canceled. Claims 1-12, 14-26 are pending.
2. The rejection of claims 12, 14-19 under 35 USC 112 second paragraph because of lacking therapeutically effective amount is dropped in view of the insertion of *effective amount* in the pharmaceutically composition.
3. The rejection of claims 20-26 under 35 USC 112 second paragraph is maintained over the now amended claims 20-26 for the following reason:

Claims 20-26 employed the term "modulating intestinal motility" which encompassed both enhancement of motility or inhibiting motility. Please note that a compound of the claims which has $\beta 3$ -agonistic activity can not be both enhancing and inhibiting simultaneously. It is recommended that the particularity be pointed out in accordance with proper descriptive support.
4. The rejection of claims 1, 10-11, 12-20 under 35 USC 102(a)(e) or (g) over Sum et al. '685 is maintained for reason of record.

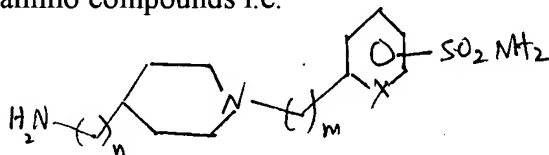
Applicants argued that a certified copy of the priority document has been submitted thus obviated the rejection since priority date must be granted.

Initially, applicants are noted that such copy although was submitted by applicants was not found in the file. Further, the certified copy does not warrant granting of priority benefit since no translation was filed. The granting of priority benefit can only be warranted when an evaluation of the certified translation to confirm that the priority application disclosed the "same" invention as now disclosed in the pending application.

In addition, even if the priority benefit is granted, it can not obviate 102(a), (e) or (f) rejections. Please note that the instant "claims" are drawn the Sum et al. '685 compounds when R₂ is SO₂NR₃R₄. A survey of the specification revealed that descriptive and enabling support of how to make such compounds are not found. Please note that the specification disclosed process

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on pages 4-9 for making the claimed compounds from an epoxide and a aminopiperidine. No disclosed on how a diamino compounds i.e.



can be employed to make the R₂ is SO₂NR₃R₄ compounds (see col. 10-14, Sum '685). Since species anticipates the genus, the Sum '685 patent constitutes 102 (a), (e), or (f) for the scope of R₂ is SO₂NR₃R₄.

5. The rejection of claims 1-5, 8, 10-11, 14-17, 20-24 under 35 USC 103(a) over Sum et al. '685 in view of Steffan et al. '901 is maintained for reason of record.

The same reasoning that the lacking of support for the R₂ is SO₂NR₃R₄ compounds as delineated supra in section 4 is also applicable here and incorporated by reference.

6. The objection of claim 9 is maintained for reason of record. Claims 6-7 which are made independent are allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang
Dec. 1, 2003


Celia Chang
Primary Examiner
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